

REMARKS

This paper is responsive to an *Official Action* that issued in this case on June 29, 2007. In that *Action*, the Examiner rejected claims 1 and 2 under 35 USC §112, ¶2. Furthermore, the Examiner finally rejected claims 1, 3, 5, 10-16, and 20-28 under 35 USC §102 as being anticipated by U.S. Pat. No. 6,470,302. All other claims were rejected under 35 USC §103 as being obvious over the '302 patent either alone or in combination with other references.

Responsive to the rejection, applicant proposes an amendment to claim 1 to address the Section 112 issues raised by the Examiner. It is believed that the amendments will overcome the Section 112 issues and, therefore, place the case in better condition for appeal. The amendment to claim 1 does not raise new issues for consideration nor will it necessitate an additional search. Entry of the amendment to claim 1 is therefore requested.

Regarding the rejections under 35 USC §112, ¶2, the Examiner alleges that:

Claim 1 is unclear and indefinite as to how "a feature of said needle and a feature of said catheter can be relative to an axis aligned with a length of said needle or said catheter if they are not one in the same."

Claim 2 is rejected for lack of antecedent basis because the phrase "said feature" is "unclear as to which said feature and how many of said features." Furthermore, claim 2 is further rejected as unclear and indefinite as "to what feature or features creates a bevel."

Applicant has no idea what the Examiner is trying to say about claim 1. Perhaps the best approach is simply to explain the old claim language, as supported by the specification. And then discuss the proposed amendment. The relevant disclosure is at paragraphs [0067] through [0072] and FIGs. 5-7.

Claim 1 recites:

a needle;
a catheter, wherein said catheter receives said needle; and
a sensor, wherein said sensor senses an angular orientation of at least one of:
(i) a feature of said needle; and
(ii) a feature of said catheter,
relative to an axis aligned with a length of said needle or said catheter.

The subject matter of claim 1 is a needle/catheter module that is disclosed in the specification. The needle/catheter module is representative of a needle/catheter that a medical practitioner would insert into a patient's arm during a vascular access procedure.

FIG. 6 depicts the "needle portion 536" and FIG. 7 depicts "catheter portion 554." FIG. 5 depicts the needle portion and catheter portion coupled together to form "needle/catheter module 218."

Unlike the prior art, the needle/catheter module that is recited in claim 1 is capable of sensing its angular orientation. It does this via sensor 538, which, as disclosed in the specification, can be two MEMS accelerometers 646 and 648.

The significance of this ability to sense angular orientation is explained at paragraph [0054], where it is indicated that in some embodiments, the simulator is capable of:

sensing the orientation of the end effector," such as to determine the orientation of a feature of the needle or catheter. In some embodiments, the feature is a bevel. This is an important aspect of the real insertion technique, since proper bevel orientation reduces a patient's discomfort during needle/catheter insertion.

It is disclosed at paragraph [0072] that in the illustrative embodiment, the bevel is preferably formed on the catheter in view of other design considerations. It is also disclosed in the specification that the bevel could alternatively be formed on the needle. Although it is of questionable benefit from the perspective of practicing vascular-access techniques with a simulation system, a bevel could be formed on both the catheter and the needle.

It should be clear from FIG. 5 that when the needle portion and catheter portion are coupled to one another, they are co-axial. It is also noted at paragraph [0069] that the needle portion 536 and the catheter portion 554 are configured for locking engagement, such as by inserting ridge 644 into a complementary slot in coupler 756 of catheter 554.

Although the specifics of the "feature" that is recited in claim 1 is not specified, it is clear that, among other possibilities (*i.e.*, in at least one embodiment) it is "bevel," since claim 2 recites that the feature is a bevel.

Returning now to the language of claim 1, the sensor senses the angular orientation of a feature (which in at least one embodiment is a bevel) of at least one of (1) the needle and (2) the catheter. So, if the feature (e.g., bevel, etc.) is on the catheter, the sensor senses the catheter's orientation. If the feature is on the needle, then the sensor senses the needle's orientation. If the bevel were on both the needle and the catheter, then they would have to be aligned with one another (since there is only one desired orientation of the bevel), which is readily done use the locking arrangement that is disclosed in the specification.

The angular orientation that is sensed is "relative to an axis aligned with a length of said needle or said catheter." This is best illustrated by the drawings below.

Assume that the needle/catheter assembly is pointing into this page. The axis in question aligns with the needle/catheter, so that it, too, is pointing into the page. In the figures below, the axis is represented by a circle. The triangle is meant to indicate the bevel, and the direction in which the apex of the bevel points is the angular orientation of the bevel.

0°

270° <-- | --> 90°

180°

0°

180°

270°

90°



Returning now to the language of claim 1, applicant proposes the following changes to try to improve the readability of the claim:

a needle;
a catheter, wherein said catheter receives said needle; and
a sensor, wherein said sensor senses an angular orientation of a
feature relative to an axis aligned with a length of *said needle*, wherein said
feature is disposed on at least one of said needle or said catheter.

The proposed amendment to claim 1 emphasizes that the "feature" —be it a "bevel" or anything else— is the same whether it is on the needle or the catheter (or even both). Also, the claim now recites that the axis is aligned with a length of the needle. Since the needle and the catheter are co-axial, the referenced axis is, by definition, also aligned with the length of the catheter. Referencing only the needle (as opposed to both the needle and the catheter) improves the readability of the claim. It is notable that the claim could recite "aligned with a length of the catheter" and it would have the same meaning.

It is believed that, if entered, the proposed amendments to claim 1 will overcome the Section 112 rejections of that claim.

Regarding claim 2, it should now be clear "what said feature and how many of them" are being recited. There appears to be some confusion on the part of the Office with respect to "what feature or features creates a bevel." The feature is the bevel. The bevel is simply the way in which the end of the catheter or the needle is cut. It has nothing to do with the relative positions of the needle and catheter. The bevel is simply a feature that is formed on the catheter or the needle.

It is believed that the amendment to claim 1 will overcome the Section 112 rejections of claims 1 and 2. It is respectfully requested that the amendment be entered to place the case in better condition for appeal.

The art rejections, which cannot stand, will be addressed on appeal.

Respectfully,
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